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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,647

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Koen Vandenbroeck

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EXAMINER

HIBBERT, CATHERINE S

ART UNIT

PAPER NUMBER

1636

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,647	<b>Applicant(s)</b> VANDENBROECK ET AL.	
	<b>Examiner</b> CATHERINE HIBBERT	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33,36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-27,31-33,36 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/6/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/6/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the First Office Action on the Merits of US Application 10/537,647, filed 28 December 2005, which is a National Stage entry of PCT/IB03/06404, filed 8 December 2003, which claims foreign priority to UK 02284651, filed 6 December 2002. Claims 34-35 and 37 are cancelled. Claims 1-33, 36 and 38-41 are pending. Claims 1-27, 31-33, 36 and 38-41 are withdrawn. Claims 28-30 are under examination in this action.

### ***Election/Restrictions***

Applicant's election without traverse of Group IV, claims 28-30, in the reply filed on 26 February 2009 is acknowledged.

Claims 1-27, 31-33, 36 and 38-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 February 2009.

### ***Claim Objections***

Claims 28-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 28, and therefore Claims 29-30 depend from Claims 17 which depends from Claim 1. However, the method of use Claim 28 does not further modify the products of Claims 17 or Claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al in "Protein disulfide isomerase-mediated cell-free assembly of recombinant interleukin-12 p40 homodimers" (Eur. J. Biochem., Vol.267, pages 6679-6683; of record) in view of Barski et al (U.S. Patent No. 6,630,324, filed 7/26/2000, see entire document, of record) and further in view of Graham et al in "Ecdysone-controlled

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expression of transgenes” (Expert Opinion on Biological Therapy, Vol. 2, June 2002, pages 525-535, of record).

Regarding Claim 28, step (i), Martens et al teach a method comprising incubating a cell culture comprising cells transfected with a baculovirus expression vector comprising DNA encoding the p40 subunit of the dimeric form of IL-12, under the control of an inducible promoter with a compound of interest to test the ability of the compound to inhibit dimer assembly ().

Regarding Claim 28, step (ii), Martens et al teach inducing transcription of the dimeric p40 IL-12 in the cells of the culture using an inducer (e.g. page 6680, left col., ¶ 1, lines 25-30).

Regarding Claim 28, step (iii) and Claim 29, Martens et al teach assaying the cell culture for the presence of secreted interleukin using a His6-p40 tag using Ni-NTA affinity chromatography (e.g. page 6680, left col., lines 18-22 and Figure 1 and legend).

Regarding Claim 30, Martens et al contemplate probing the cell culture with an antibody specific to a p40 subunit of the dimeric IL-12 (e.g. page 6680, right col., ¶ headed: “p40 ELISA” and “Nonreducing SDS/PAGE and immunoblot”).

However, Martens et al differ from the instant invention in that Martens et al fail to teach the use of an ecdysone-inducible promoter expression system.

Barski et al (U.S. Patent No. 6,630,324, filed 7/26/2000, see entire document, or record) teach vectors for inducible protein expression. Barski et al teach that embodiments of the expression vector can comprise an ecdysone-inducible promoter expression system (see column 24, lines 36-50, in particular). Barski et al teach an

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embodiment in which the expression vector comprises a sequence encoding a p35 and the p40 subunit of IL-12 (see column 62, lines 46-54, in particular). Therefore, Barski *et al* contemplate host cell lines transfected with at least an expression vector comprising a sequence encoding a p35 and the p40 subunit of IL-12. Barski *et al* contemplate using their inducible protein expression systems for screening assay tools. In the case of the ecdysone-inducible promoter, the induction would inherently comprise the addition of ecdysone or an ecdysone analog (e.g. see Graham *et al* entire reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the ecdysone-inducible expression system of Barski *et al* in the method taught in Martens *et al* because Barski *et al* teach that their vectors encoding a p35 and the p40 subunit of IL-12 were available and were successfully used (e.g. column 62, lines 46-54).

One would have been motivated at the time the invention was made to have utilized the ecdysone-inducible expression system of Barski *et al*. in the method of Martens *et al* because Graham *et al* cite numerous benefits to using the ecdysone-inducible expression system, including showing “great potential for use in human gene therapy”, stating systems based on insect ecdysone receptors are particularly promising candidates” and are particularly safe for use in animals (see abstract and p.529, right col., ¶ 2, lines 1-8). In addition, both Martens *et al*. and Barski *et al*. are in the same field of endeavor (expression vectors for) and both are directed to the same problem sought to be solved (testing compounds that affect the dimerization of subunits of IL-12 using expression vector systems).

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Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when utilizing the ecdysone-inducible expression system (as taught by Graham et al and Barski et al) in the standard screening method of Martens et al.

In view of the foregoing, the method of claims 28-30, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC §103(a).

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine Hibbert  
Examiner/AU1636

/ Christopher S. F. Low /  
Supervisory Patent Examiner, Art Unit 1636